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For:	H	lealth Servic	es 608-2	266-3262		By/Representing:	Alex Ignatowski		
May C	ontact:					Drafter:	mduchek		
Subject: Health - abortion/maternal/child						Addl. Drafters:			
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May Co	ntact:				Drafter:	mduchek	
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Bill

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Wanted:	As tin	ne permits			Same as LRB:		
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May Contact:	:				Drafter:	mduchek	
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Bill

Received:

11/21/2013

Received By:

mduchek

Wanted:

As time permits

Same as LRB:

For:

Health Services 608-266-3262

By/Representing:

Alex Ignatowski

May Contact:

Drafter:

mduchek

Subject:

Health - abortion/maternal/child

Addl. Drafters:

Extra Copies:

Submit via email:

YES

Requester's email:

alex.ignatowski@wisconsin.gov

Carbon copy (CC) to:

Pre Topic:

No specific pre topic given

Topic:

Infant tests for congenital disorders \checkmark

Instructions:

See attached

Drafting History:

Vers. Drafted

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Jacketed

Required

/? mduchek

FE Sent For:

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Draft 10-17-13

253.13 Tests for congenital disorders.

- (1) BLOOD-TESTS. The attending physician or nurse licensed under s. 441.15 shall cause every infant born in each hospital or maternity home, prior to its discharge therefrom, to be subjected to blood tests for congenital and metabolic disorders, as specified in rules promulgated by the department. If the infant is born elsewhere than in a hospital or maternity home, the attending physician, nurse licensed under s. 441.15 or birth attendant who attended the birth shall cause the infant, within one week of birth, to be subjected to these blood-tests.
- (1m) URINE TESTS. The department may establish a urine test program to test infants for causes of congenital disorders. The state laboratory of hygiene board may establish the methods of obtaining urine specimens and testing such specimens, and may develop materials for use in the tests. No person may be required to participate in programs developed under this subsection.
- (2) TESTS; DIAGNOSTIC, DIETARY AND FOLLOW-UP COUNSELING PROGRAM; FEES. The department shall contract with the state laboratory of hygiene to perform the laboratory tests specified under this section and to furnish materials for use in the tests. The department shall provide necessary diagnostic services, special dietary treatment as prescribed by a physician for a patient with a congenital disorder as identified by tests under sub. (1) or (1m) and follow-up counseling for the patient and his or her family. The department shall impose a fee, by rule, for tests performed under this section sufficient to pay for services provided under the contract. The department shall include as part of the fee established by rule amounts to fund the provision of diagnostic and counseling services, special dietary treatment, and periodic evaluation of infant screening programs, the costs of consulting with experts under sub. (5), the costs of administering the hearing screening program under s. 253.115, and the costs of administering the congenital disorder program under this section and shall credit these amounts to the appropriation accounts under s. 20.435 (1) (ja) and (jb).
- (3) EXCEPTIONS. This section shall not apply if the parents or legal guardian of the child object thereto on the grounds that the test conflicts with their religious tenets and practices, or with their personal convictions. No tests may be performed under sub. (1) or (1m) unless the parents or legal guardian are fully informed of the purposes of testing under this section and have been given reasonable opportunity to object as authorized in this subsection or in sub. (1m) to such tests.
- (4) CONFIDENTIALITY OF TESTS AND RELATED INFORMATION. (a)The state laboratory of hygiene shall provide the <u>laboratory</u> test results to the physician, who shall advise the parents or legal guardian of the results. No information obtained under this section from the parents or guardian or from specimens from the infant testing may be disclosed except for use in statistical data compiled by the department without reference to the identity of any individual and except as provided in s. <u>146.82 (2)</u>. The state laboratory of hygiene board shall provide to the department the names and addresses of parents of infants who have positive test results. (b) The department may require reporting for use in statistical data compiledation and for evaluation of infant screening programs.
- (5) RELATED SERVICES. The department shall disseminate information to families whose children suffer from congenital disorders and to women of child-bearing age with a history of congenital disorders concerning the need for and availability of follow-up counseling and special dietary treatment and the necessity for testing infants. The department shall also refer families of children who suffer from congenital disorders to available health services programs and shall coordinate the provision of these programs. The department shall periodically consult appropriate experts in reviewing and evaluating the state's infant screening programs.

History: 1977 c. 160; 1983 a. 157; 1985 a. 255; 1987 a. 27; 1989 a. 31; 1991 a. 39, 177; 1993 a. 27 s. 316; Stats. 1993 s. 253.13; 1995 a. 27 s. 9126 (19); 2001 a. 16, 52; 2007 a. 20 s. 9121 (6) (a); 2009 a. 28, 279; 2011 a. 32. Cross-reference: See also ch. DHS 115, Wis. adm. code.

A physician and parent may enter an agreement to perform a PKU test after the infant has left the hospital without violating sub. (1). 61 Atty. Gen. 66.

Formatted: Highlight

Comment [31]: Would this language be appropriate since the department is charged to evaluate infant screening programs (see highlight)?

Duchek, Michael

From:

112/14. Call from repeated of Alex. Ox asis for factoring Ignatowski, Alex - DHS <Alex.Ignatowski@dhs.wisconsin.gov>

Sent:

Tuesday, November 26, 2013 8:59 AM

To:

Duchek, Michael

Subject:

RE: Request for Legislative Drafting

Hi Mike –

Please see the answers to your questions below:

- 1. The idea is, as I understand it, to add point-of-care testing to the statute by eliminating the limitation that they be blood tests. In the case of point-of-care testing, I assume that the State Lab of Hygiene is not necessarily involved and that the hospital staff or whoever would be doing the test. Is that correct? If so, would it be more accurate to refer in the statutes to what the State Lab of Hygiene is doing as "conducting laboratory testing" (on the specimens to obtain test results for any tests that require such laboratory testing)? The State Lab of Hygiene will not be involved in point of care testing.
- 2. 253.13 (2) requires a fee to be charged for the tests. Should the fee still be charged for point-of-care tests? The current statute seems to say that the fee would be required for any such test so I wanted to make sure that would still be appropriate for point-of-care tests. There is a single newborn screening fee, paid by hospitals when they purchase the test cards. This fee covers all tests run at the state lab, as well as follow-up and some care (e.g. medical nutrition) for affected individuals, and program evaluation. Any follow-up and evaluation of point of care tests would also be covered by this same fee.
- 3. Something was highlighted in yellow in s. 253.13 (2). Was a change wanted here? See answer to question 4.
- 4. In s. 253.13 (4), a paragraph (b) is scored in. Is this referring to reporting of test results or would that be too specific? That would be too specific. The department may need additional information, such as whether a referral was made, in order to fulfill the charge of "evaluation of infant screening programs" (see highlighted text in 253.13 (2)). For lab tests, we can monitor this through the lab, which makes the referral calls. For pointof-care testing, we may need to collect in another way.
- 5. I assume you want to leave the newborn hearing screening statute alone (s. 253.115), but thought I'd check just in case. Correct - no change to the hearing statute.

Thanks again for your work on this and please let me know if you have any other questions.

-Alex

Alex Ignatowski

Legislative Advisor

Department of Health Services

Office: 608-266-3262 Mobile: 608-301-6149

alex.ignatowski@wisconsin.gov

From: Duchek, Michael [mailto:Michael.Duchek@legis.wisconsin.gov]

Sent: Friday, November 22, 2013 2:16 PM

To: Ignatowski, Alex - DHS

Subject: RE: Request for Legislative Drafting

Alex,

I have read through the language request and some of the report, and I think I mostly understand it. In the interest of getting you what you want sooner though, I thought I'd provide the following questions:

- 1. The idea is, as I understand it, to add point-of-care testing to the statute by eliminating the limitation that they be blood tests. In the case of point-of-care testing, I assume that the State Lab of Hygiene is not necessarily involved and that the hospital staff or whoever would be doing the test. Is that correct? If so, would it be more accurate to refer in the statutes to what the State Lab of Hygiene is doing as "conducting laboratory testing" (on the specimens to obtain test results for any tests that require such laboratory testing)?
- 2. 253.13 (2) requires a fee to be charged for the tests. Should the fee still be charged for point-of-care tests? The current statute seems to say that the fee would be required for any such test so I wanted to make sure that would still be appropriate for point-of-care tests.
- 3. Something was highlighted in yellow in s. 253.13 (2). Was a change wanted here?
- 4. In s. 253.13 (4), a paragraph (b) is scored in. Is this referring to reporting of test results or would that be too specific?
- 5. I assume you want to leave the newborn hearing screening statute alone (s. 253.115), but thought I'd check just in case.

Thanks,

Mike Duchek Legislative Attorney Wisconsin Legislative Reference Bureau (608) 266-0130

From: LRB.Legal

Sent: Thursday, November 21, 2013 12:39 PM

To: Dodge, Tamara; Duchek, Michael

Subject: FW: Request for Legislative Drafting

Sarah Basford

Senior Program Assistant Legislative Reference Bureau 1 East Main St., Suite 200 Madison, WI 53703 (608) 266-3561

From: Ignatowski, Alex - DHS [mailto:Alex.Ignatowski@dhs.wisconsin.gov]

Sent: Thursday, November 21, 2013 12:36 PM

To: LRB.Legal

Cc: O'Day, Renee C - DHS

Subject: Request for Legislative Drafting

To whom it may concern,

On behalf of DHS, I am requesting legislation to be drafted to add "point of care" testing to the "Test for congenital disorders" statute under Wis. Stat. Ch 253.13. Currently, only blood test are allowed to be considered by the Department. I have attached a copy of what our Office of Legal Counsel drafted for consideration. Below, I have also included what was in the Newborn Screening Task Force Report (also attached) as another point of reference. Please let me know if you have any questions.

Adding point-of-care testing to the congenital disorders statute would allow point-of-care newborn screening to be reviewed under the criteria set forth by the administrative rule and not require legislation for each disorder.

Regards,

Alex

Alex Ignatowski

Legislative Advisor
Department of Health Services

Office: 608-266-3262 Mobile: 608-301-6149

alex.ignatowski@wisconsin.gov



State of Misconsin 2013 - 2014 LEGISLATURE



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PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

AN ACT ...; relating to: tests administered on newborns for congenital disorders.

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a subsequent version of this draft.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 253.13 (1), (2) and (3) of the statutes are amended to read:

253.13 (1) BLOOD TESTS TESTS: REQUIREMENTS. The attending physician or nurse licensed under s. 441.15 shall cause every infant born in each hospital or maternity home, prior to its discharge therefrom, to be subjected to blood tests for congenital and metabolic disorders, as specified in rules promulgated by the department. If the infant is born elsewhere than in a hospital or maternity home, the attending physician, nurse licensed under s. 441.15, or birth attendant who attended the birth shall cause the infant, within one week of birth, to be subjected to these blood tests.

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1	(2) Tests; diagnostic, dietary and follow-up counseling program; fees. The
2	department shall contract with the state laboratory of hygiene to perform the any
3	tests specified under this section that are laboratory tests and to furnish materials
4	for use in the tests. The department shall provide necessary diagnostic services,
5	special dietary treatment as prescribed by a physician for a patient with a congenital
6	disorder as identified by tests under sub. (1) or (1m) this section, and follow-up
7	counseling for the patient and his or her family. The department shall impose a fee,
8	by rule, for tests performed under this section sufficient to pay for services provided
9	under the contract. The department shall include as part of the fee established by
10	rule amounts to fund the provision of diagnostic and counseling services, special
11	dietary treatment, and periodic evaluation of infant screening programs, the costs
12	of consulting with experts under sub. (5), the costs of administering the hearing
13	screening program under s. 253.115, and the costs of administering the congenital
14	disorder program under this section and shall credit these amounts to the
15	appropriation accounts under s. 20.435 (1) (ja) and (jb).

****NOTE: Would it be more accurate here to describe what the State Lab of Hygfine is doing as "conducting laboratory testing" or "providing laboratory test results"?

****NOTE: Since we are repealing sub. (1m), I simply referred here and in sub. (3) to tests "under this section" to be consistent with other references in this section. (Is that OK?)

(3) EXCEPTIONS. This section shall not apply if the parents or legal guardian of the child object thereto on the grounds that the test conflicts with their religious tenets and practices or with their personal convictions. No tests may be performed under sub. (1) or (1m) this section unless the parents or legal guardian are fully informed of the purposes of testing under this section and have been given

1	reasonable opportunity to object as authorized in this subsection or in sub. (1m) to
2	such tests.
3	History: 1977 c. 160; 1983 a. 157; 1985 a. 256 1987 a. 27; 1989 a. 31; 1991 a. 39, 177; 1993 a. 27 s. 316; Stats. 1993 s. 253.13; 1995 a. 27 s. 9126 (19); 2001 a. 16, 52; 2007 a. 20 s. 9121 (6) (a); 2009 a. 28, 279; 2011 32. SECTION 2. 253.13 (1m) of the statutes is repealed.
4	SECTION 3. 253.13 (4) (title) of the statutes is amended to read:
5	253.13 (4) (title) Confidentiality of tests and related information reporting.
6	History: 1977 c. 160; 1983 a. 157; 1985 a. 255; 1987 a. 27; 1989 a. 31; 1991 a. 39, 177; 1993 a. 27 s. 316; Stats. 1993 s. 253.13; 1995 a. 27 s. 9126 (19); 2001 a. 16, 52; 2007 a. 20 s. 9121 (6) (a); 2009 a. 28, 279; 2017 a. 32. SECTION 4. 253.13 (4) of the statutes is renumbered 253.13 (4) (a) and amended
7	to read:
8	253.13 (4) (a) The state laboratory of hygiene shall provide the its laboratory
9	test results to the physician, who shall advise the parents or legal guardian of the
LO	results. No information obtained under this section from the parents or guardian or
11	from specimens from the infant tests performed under this section may be disclosed
12	except for use in statistical data compiled by the department without reference to the
13	identity of any individual and except as provided in s. 146.82 (2). The state
14	laboratory of hygiene board shall provide to the department the names and
15	addresses of parents of infants who have positive test results.
	History: 1977 c. 160; 1983 a. 157; 1985 a. 255; 1987 a. 27; 1989 a. 31; 1991 a. 39, 177; 1993 a. 27 s. 316; Stats. 1993 s. 253.13; 1995 a. 27 s. 9126 (19); 2001 a. 16, 52; 2007 a. 20 s. 9121 (6) (a); 2009 a. 28, 279; 2011 a. 32. ****NOTE: I said "tests performed under this section" here. Let me know if that is incorrect.
16	SECTION 5. 253.13 (4) (b) of the statutes is created to read:
17	253.13 (4) (b) The department may require reporting in connection with the

253.13 (4) (b) The department may require reporting in connection with the tests performed under this section for use in statistical data compilation and for evaluation of infant screening programs.

20 (END)

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State of Misconsin 2013 - 2014 LEGISLATURE



PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

AN ACT to repeal 253.13 (1m); to renumber and amend 253.13 (4); to amend 253.13 (1), (2) and (3) and 253.13 (4) (title); and to create 253.13 (4) (b) of the statutes; relating to: tests administered to newborns for congenital disorders.

Analysis by the Legislative Reference Bureau

9 lus Analysis

This is a preliminary draft. An analysis will be provided in a subsequent version of this draft.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 253.13 (1), (2) and (3) of the statutes are amended to read:

253.13 (1) BLOOD TESTS TESTS; REQUIREMENTS. The attending physician or nurse licensed under s. 441.15 shall cause every infant born in each hospital or maternity home, prior to its discharge therefrom, to be subjected to blood tests for congenital and metabolic disorders, as specified in rules promulgated by the department. If the infant is born elsewhere than in a hospital or maternity home, the attending



physician, nurse licensed under s. 441.15, or birth attendant who attended the birth shall cause the infant, within one week of birth, to be subjected to these blood tests.

(2) Tests; diagnostic, dietary and follow-up counseling program; fees. The department shall contract with the state laboratory of hygiene to perform the any tests specified under this section that are laboratory tests and to furnish materials for use in the tests. The department shall provide necessary diagnostic services, special dietary treatment as prescribed by a physician for a patient with a congenital disorder as identified by tests under sub. (1) or (1m) this section, and follow-up counseling for the patient and his or her family. The department shall impose a fee, by rule, for tests performed under this section sufficient to pay for services provided under the contract. The department shall include as part of the fee established by rule amounts to fund the provision of diagnostic and counseling services, special dietary treatment, and periodic evaluation of infant screening programs, the costs of consulting with experts under sub. (5), the costs of administering the hearing screening program under s. 253.115, and the costs of administering the congenital disorder program under this section and shall credit these amounts to the appropriation accounts under s. 20.435 (1) (ja) and (jb).

****Note: Would it be more accurate here to describe what the State Lab of Hygiene is doing as "conducting laboratory testing" or "providing laboratory test results"?

****NOTE: Since we are repealing sub. (1m), I simply referred here and in sub. (3) to tests "under this section" to be consistent with other references in this section.

(3) EXCEPTIONS. This section shall not apply if the parents or legal guardian of the child object thereto on the grounds that the test conflicts with their religious tenets and practices or with their personal convictions. No tests may be performed under sub. (1) or (1m) this section unless the parents or legal guardian are fully informed of the purposes of testing under this section and have been given

1	reasonable opportunity to object as authorized in this subsection or in sub. (1m) to
2	such tests.
3	SECTION 2. 253.13 (1m) of the statutes is repealed.
4	SECTION 3. 253.13 (4) (title) of the statutes is amended to read:
5	253.13 (4) (title) Confidentiality of tests and related information reporting.
6	SECTION 4. 253.13 (4) of the statutes is renumbered 253.13 (4) (a) and amended
7	to read:
8	253.13 (4) (a) The state laboratory of hygiene shall provide the its laboratory
9	test results to the physician, who shall advise the parents or legal guardian of the
10	results. No information obtained under this section from the parents or guardian or
11	from specimens from the infant tests performed under this section may be disclosed
12	except for use in statistical data compiled by the department without reference to the
13	identity of any individual and except as provided in s. 146.82 (2). The state
14	laboratory of hygiene board shall provide to the department the names and
15	addresses of parents of infants who have positive test results.
16	Section 5. 253.13 (4) (b) of the statutes is created to read:
17	253.13 (4) (b) The department may require reporting in connection with the
18	tests performed under this section for use in statistical data compilation and for
19	evaluation of infant screening programs.

(END)

2013-2014 DRAFTING INSERT FROM THE LEGISLATIVE REFERENCE BUREAU

INS ANALYSIS

Under current law, blood tests for congenital and metabolic disorders (infant blood tests), as specified in rules promulgated by the Department of Health Services (DHS), must be performed on every infant born in a hospital or maternity home prior to the infant's discharge. If an infant is born elsewhere than in a hospital or maternity home, these infant blood tests must be performed within one week of birth. Also under current law, DHS may establish a urine testing program to test infants for causes of congenital disorders (infant urine testing program), in which no person is required to participate. DHS must, under current law, contract with the State Laboratory of Hygiene (SLH) to perform any required infant tests and to furnish materials for use in those tests and must, by rule, impose a fee for infant testing to cover various specified costs. Current law imposes confidentiality requirements on information obtained from parents or a legal guardian in connection with infant testing or obtained from infant testing specimens.

This bill eliminates the provision related to establishing an infant urine testing program and modifies the provision relating to infant blood tests so that the required tests, as specified in rules promulgated by DHS, may be any kind of test. Information obtained from these required infant tests are subject to the same confidentiality requirements as under current law. The bill provides that DHS must contract with the SLH to perform any required infant tests that are laboratory tests and to furnish materials for use in the tests. The bill also provides that DHS may require reporting in connection with any required infant tests for use in statistical data compilation and for evaluation of infant screening programs. The bill does not affect provisions

in current law relating to newborn hearing screenings!

Also under current law, the infant blood test and infant urine testing program provisions do not apply if the parents or legal guardian of the child object on the grounds that the test conflicts with their religious tenets and practices. The bill retains this provision with respect to any required infant tests and provides that, in addition, the parents or legal guardian of the child may object on the grounds that a required infant test conflicts with their personal convictions.

For further information see the state fiscal estimate, which will be printed as

an appendix to this bill.

Barman, Mike

From:

Ignatowski, Alex - DHS <Alex.Ignatowski@dhs.wisconsin.gov>

Sent: Wednesday, January 08, 2014 3:12 PM

To: Subject: LRB.Legal; Duchek, Michael

Re: Draft review: LRB -3697/1 Topic: Infant tests for congenital disorders

Hi Mike - I will ask to have this jacketed in the Assembly; can I have a companion drafted as well?

Thanks,

Alex

On Jan 8, 2014, at 3:05 PM, "LRB.Legal" < lrblegal@legis.wisconsin.gov> wrote:

State of Wisconsin - Legislative Reference Bureau

One East Main Street - Suite 200 - Madison

The attached draft was prepared at your request. Please review it carefully to ensure that it satisfies your intent. If you have any questions concerning the draft or would like to have it redrafted, please contact Michael Duchek, Legislative Attorney, at (608) 266-0130, at michael.duchek@legis.wisconsin.gov, or at One East Main Street, Suite 200.

If you would like to jacket the draft for introduction, please click on the appropriate button below. Please select only one button. If you wish to introduce this draft in both houses please contact the drafting attorney to have a companion bill drafted.



Please allow one day for jacketing. If this is a "rush" please make a note in your response e-mail so we are aware that we need to give this request a high priority.

If the last paragraph of the analysis states that a fiscal estimate will be prepared, the LRB will submit a request to DOA when the draft is introduced. You may obtain a fiscal estimate on the draft prior to introduction by contacting our program assistants at LRB.Legal@legis.wisconsin.gov or at (608) 266-3561. If you requested a fiscal estimate on an

<u>LRB.Legal@legis.wisconsin.gov</u> or at (608) 266-3561. If you requested a fiscal estimate on an earlier version of this draft and would like to obtain a fiscal estimate on the current version before it is introduced, you will need to request a revised fiscal estimate from our program assistants.

Please call our program assistants at (608) 266-3561 if you have any questions regarding this email.

<13-3697_1.pdf>

Rose, Stefanie

From:

Ignatowski, Alex - DHS <Alex.Ignatowski@dhs.wisconsin.gov>

Sent:

Wednesday, January 08, 2014 3:16 PM

To:

LRB.Legal

Subject:

Draft Review: LRB -3697/1 Topic: Infant tests for congenital disorders

Please Jacket LRB -3697/1 for the ASSEMBLY. I would like to pick up the draft tomorrow morning if possible.

Thanks!